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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,746	01/25/2001	David H. Mowry	11587.40US01	5109

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,746	MOWRY, DAVID H.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14-20 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *4-6,9,10,14-20 and 26-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7, 8, and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a response to the amendment dated June 16, 2004. Claims 1-3, 7, 8 and 22-25 are under consideration.

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Applicant has amended independent claims 1 and 24 to state that the passageway extending into the heart between the heart chamber and the first coronary vessel is a preexisting natural septal opening. Applicant then argues that this defines over the prior art rejection. Applicant is directed to the current application specification where pages 16-17 recite, "In situation where an existing opening is used, such as the septal branches 160, 162, the pathway to the heart chamber must be extended to establish communication with the heart chamber 150. For example, as shown in FIG. 4D, a pathway extension 163 can be formed to complete the path to the heart chamber 150. To accomplish this, the catheter device 102 can be equipped with (or used in conjunction with a catheter equipped with) an ablation device, for example, an ablation tip (not shown) capable of ablating or otherwise creating the channel pathway extension 163 between either of the septal branches 160, 162 into the heart chamber 150." Given this recitation, some portion of the channel must be created. Therefore, although Wilk does not explicitly recite to use a preexisting natural opening, it would be obvious to one with ordinary skill in the art and within the scope of the invention to use a preexisting opening for the purpose of less drilling. The path of least resistance would be to use an

area where there would be less channel formation required and this would be obvious to one with ordinary skill in the art at the time the invention was made. The rejection is reiterated below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 7, 8 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in US Patent No. 5,409,019.

Regarding claim 1, Wilk discloses a method for supplementing flow of blood to a portion of the cardiovascular system of a patient via inserting a catheter device (20) into the vasculature of the patient and advancing the catheter device to a first location within a first coronary vessel (CA) within the cardiovascular system and forming a blood flow path (@12) from a heart chamber directly to the first coronary vessel via a septal passageway (created by a drill) extending into the heart wall between the heart chamber and the first coronary vessel, as recited in the abstract, columns 4-6 and seen in figures 1-8.

However, Wilk does not explicitly recite a preexisting natural opening. Applicant is directed to the current application specification where pages 16-17 recite, "In situation where an existing opening is used, such as the septal branches 160, 162, the pathway

to the heart chamber must be extended to establish communication with the heart chamber 150. For example, as shown in FIG. 4D, a pathway extension 163 can be formed to complete the path to the heart chamber 150. To accomplish this, the catheter device 102 can be equipped with (or used in conjunction with a catheter equipped with) an ablation device, for example, an ablation tip (not shown) capable of ablating or otherwise creating the channel pathway extension 163 between either of the septal branches 160, 162 into the heart chamber 150." Given this recitation, some portion of the channel must be created. Therefore, although Wilk does not explicitly recite to use a preexisting natural opening, it would be obvious to one with ordinary skill in the art and within the scope of the invention to use a preexisting opening for the purpose of less drilling. The path of least resistance would be to use an area where there would be less channel formation required and this would be obvious to one with ordinary skill in the art at the time the invention was made.

Regarding claim 2, Wilk, as modified, discloses that as applied to claim 1, as well as, forming a blood flow path from the heart chamber directly to the first coronary vessel via placing a conduit (such as 12) in a heart wall between the heart chamber and the first coronary vessel.

Regarding claim 3, Wilk, as modified, discloses that as applied to claim 2, as well as, placing the conduit in the heart wall between the heart chamber and the first coronary

vessel a conduit is placed in a septal passageway (in the heart wall), as recited in column 3, lines 55-68 and column 4.

Regarding claim 7, Wilk, as modified, discloses that as applied to claim 1, as well as, a first coronary vessel that is a coronary artery (CA), as discussed throughout.

Regarding claim 8, Wilk, as modified, discloses that as applied to claim 7, as well as, a coronary artery that is a left anterior descending coronary artery, as seen in figures 1-3A.

Regarding claims 22 and 23, Wilk discloses that as applied to claim 22. However, Wilk does not explicitly recite distending the obstruction within the coronary artery via inflating a balloon at the obstruction within the coronary vessel, aka angioplasty. On the other hand, angioplasty is extraordinarily well known in the art. Thus, it would be obvious to one with ordinary skill in the art to in addition to moving past the occlusion to also perform angioplasty for the purpose of compressing the plaque against the wall to clear a larger space.

Regarding claim 24, Wilk discloses a method for supplementing a flow of blood to a portion of the cardiovascular system of a patient, via inserting a catheter device (20) into the vasculature of the patient and advancing the catheter device to a first location within a coronary vessel within the cardiovascular system, the first location being

proximate (just past the blockage as recited in column 4, lines 15-30 and not unlike applicant's depiction) to an obstruction within the coronary vessel (CA); advancing the catheter device through the obstruction to a second position distal to the obstruction, as discussed in column 4; guiding the catheter device through an interstitial passageway extending into a heart wall between a heart chamber and the coronary vessel; and placing a conduit (via 12) in the interstitial passageway extending into the heart wall between the heart chamber and the coronary vessel, wherein the intestinal passageway includes a septal passageway (created by a drill) extending into the heart wall between the heart chamber and the coronary vessel, as recited in columns 3-6 and seen in figures 1-8.

However, Wilk does not explicitly recite a preexisting natural opening. Applicant is directed to the current application specification where pages 16-17 recite, "In situation where an existing opening is used, such as the septal branches 160, 162, the pathway to the heart chamber must be extended to establish communication with the heart chamber 150. For example, as shown in FIG. 4D, a pathway extension 163 can be formed to complete the path to the heart chamber 150. To accomplish this, the catheter device 102 can be equipped with (or used in conjunction with a catheter equipped with) an ablation device, for example, an ablation tip (not shown) capable of ablating or otherwise creating the channel pathway extension 163 between either of the septal branches 160, 162 into the heart chamber 150." Given this recitation some portion of the channel must be created. Therefore, although Wilk does not explicitly recite to use a preexisting natural opening, it would be obvious to one with ordinary skill in the art and

within the scope of the invention to use a preexisting opening for the purpose of less drilling. The path of least resistance would be to use an area where there would be less channel formation required and this would be obvious to one with ordinary skill in the art at the time the invention was made.

Regarding claim 25, Wilk, as modified, discloses that as applied to claim 24, as well as, a coronary vessel that is a coronary artery (CA), as discussed throughout.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700